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Subject: File

PLAINTIFFS TRIAL EXHIBIT
P-12883_00001

Controlled Substance Regulatory Org Structure

Background

- Existing CS regulatory staff – 6 people
  - NE & South- 2 people each
  - NC & West – 1 person each
- Prior CSMP process heavily dependent on sales and ops
  - Inconsistent
  - Competency
  - Conflict of objectives
- Prior program limited ability for pharmacy site visits by regulatory
- Span of control

[redacted]

Future Requirements

- Program redesign driving several areas
  - Larger field level presence
    - Increased number of regulatory site visits
    - Skilled in evaluating pharmacy "corresponding responsibility"
    - Reviewing daily output of suspicious order report
    - Frequent and detailed review of analytics
    - Closer review of record keeping and reporting (ARCOS)
  - Supervision skilled in controlled substance regulatory compliance and diversion investigation
  - Dedicated analytics support
    - Routine reporting
    - Ad Hoc reporting – eg. Deep dive analysis

Future Requirements (cont)

- Dedicated management of RNA
  - Focus on interaction with RNA HQ
  - Monitor at store level
  - Manage suspicious order reporting and thresholds
- Day to Day Management Oversight
  - Second level approval for changes in threshold outside the guidelines
  - Subject matter expertise for frontline staff